BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: **SOLOVAY, K. ET AL**

Serial No. **10/713,873**

Filed: **November 14, 2003**

For: **RAIL STENT**

Art Unit: **3773**
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APPELLANT'S APPEAL BRIEF

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I. REAL PARTY IN INTEREST.

The real party in interest is GMP Surgical Solutions, Inc., a subsidiary of GMP Companies, Inc. The assignee is in discussions with Michael J. Keller, the undersigned patent attorney of record, regarding assignment of this application to Michael J. Keller.

II. RELATED APPEALS AND INTERFERENCES.

Appellant, Appellant's legal representative and Assignee of the subject application is not aware of any other prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

An amendment to the claims was filed on August 15, 2007 and was entered by the Examiner. Claims 1-20 remain pending in the application with Claim 1 having been amended. All claims are being appealed. The below listing of the claims reflects the amendments filed on August 15, 2007.

Listing of Claims Entered by Amendment of August 15, 2007:

1. (Previously Presented) A stent for introducing within a body comprising: a plurality of vessel support elements having at least one aperture therethrough for the passage of at least one support rail, a first one of said vessel support elements forming a first end support element and second one of said support elements forming a second end support element; and wherein the at least one support rail element extending between said end support elements and including a curved end section for extending beyond one of the end support elements, wherein a plurality of said vessel support elements are moveable along and relative to said at least one support rail element.

2. (Original) The stent according to claim 1, wherein said at least one support rail element includes a plurality of curved end sections.

3. (Original) The stent according to claim 2, wherein said at least one support rail element includes a plurality of elongated sections extending between the curved end sections located at opposite ends of said stent.

4. (Original) The stent according to claim 3, wherein said elongated sections are integrally connected to each other by respective curved end sections.

5. (Original) The stent according to claim 4, wherein said stent includes a single support rail element that extends along multiple axes of said stent, said axes being substantially parallel to the longitudinal axis of the stent.

6. (Original) The stent according to claim 2, wherein said at least one support rail element includes a single elongated member extending between respective curved end sections, and wherein said respective curved end sections have terminal ends secured to a respective one of said vessel support elements.

7. (Original) The stent according to claim 1, wherein said at least one support rail element comprises a plurality of elongated sections and a curved section extending between said elongated sections.

8. (Original) The stent according to claim 7, wherein said elongated sections each have a first end secured to the first end support element and a second end integral with said curved section.

9. (Original) The stent according to claim 8, wherein said second ends of said elongated sections are free of a direct connection to said second end support element.

10. (Original) The stent according to claim 1, wherein said at least one support rail element comprises a support rail element that has a terminus secured to a vessel support element positioned between said first end support element and said second end support element.

11. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a biocompatible material.

12. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a base material having a biocompatible covering.

13. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising at least one agent for delivery to the body.

14. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a base material having a coating of at least one agent for delivery to the body.

15. (Previously Presented) The stent according to claim 13 wherein the support rails consist of a polymer comprising at least one agent for delivery to the body.

16. (Previously Presented) The stent according to claim 13 wherein the vessel support element and support rail are each coated with a different agent for delivery to the body.

17. (Previously Presented) The stent according to claim 13 wherein each of the rail support elements comprises a different agent for delivery to the body.

18. (Previously Presented) The stent according to claim 14 wherein the support rails consist of a polymer comprising at least one agent for delivery to the body.

19. (Previously Presented) The stent according to claim 14 wherein the vessel support element and support rail are each coated with a different agent for delivery to the body.

20. (Previously Presented) The stent according to claim 14 wherein each of the rail support elements comprises a different agent for delivery to the body.

IV. STATUS OF AMENDMENTS.

Pursuant to 37 C.F.R. §1.116, an amendment after a final action was filed on July 8, 2008 amending the claims to place the claims in condition for allowance or to present the rejected claims in better form for consideration on appeal. Claim 1was amended on August 15, 2007. Claims 2-19 were previously presented. On February 28, 2008, the Examiner issued an Advisory Action advising maintaining the final rejection. The proposed amendments are repeated below.

Listing of Claims:

1. (Previously Presented) A stent for introducing within a body comprising: a plurality of vessel support elements having at least one aperture therethrough for the passage of at least one support rail, a first one of said vessel support elements forming a first end support element and second one of said support elements forming a second end support element; and wherein the at least one support rail element extending between said end support elements and including a curved end section for extending beyond one of the end support elements, wherein a plurality of said vessel support elements are moveable along and relative to said at least one support rail element.

2. (Original) The stent according to claim 1, wherein said at least one support rail element includes a plurality of curved end sections.

3. (Original) The stent according to claim 2, wherein said at least one support rail element includes a plurality of elongated sections extending between the curved end sections located at opposite ends of said stent.

4. (Original) The stent according to claim 3, wherein said elongated sections are integrally connected to each other by respective curved end sections.

5. (Original) The stent according to claim 4, wherein said stent includes a single support rail element that extends along multiple axes of said stent, said axes being substantially parallel to the longitudinal axis of the stent.

6. (Original) The stent according to claim 2, wherein said at least one support rail element includes a single elongated member extending between respective curved end sections, and wherein said respective curved end sections have terminal ends secured to a respective one of said vessel support elements.

7. (Original) The stent according to claim 1, wherein said at least one support rail element comprises a plurality of elongated sections and a curved section extending between said elongated sections.

8. (Original) The stent according to claim 7, wherein said elongated sections each have a first end secured to the first end support element and a second end integral with said curved section.

9. (Original) The stent according to claim 8, wherein said second ends of said elongated sections are free of a direct connection to said second end support element.

10. (Original) The stent according to claim 1, wherein said at least one support rail element comprises a support rail element that has a terminus secured to a vessel support element positioned between said first end support element and said second end support element.

11. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a biocompatible material.

12. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a base material having a biocompatible covering.

13. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising at least one agent for delivery to the body.

14. (Original) The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a base material having a coating of at least one agent for delivery to the body.

15. (Previously Presented) The stent according to claim 13 wherein the support rails consist of a polymer comprising at least one agent for delivery to the body.

16. (Previously Presented) The stent according to claim 13 wherein the vessel support element and support rail are each coated with a different agent for delivery to the body.

17. (Previously Presented) The stent according to claim 13 wherein each of the rail support elements comprises a different agent for delivery to the body.

18. (Previously Presented) The stent according to claim 14 wherein the support rails consist of a polymer comprising at least one agent for delivery to the body.

19. (Previously Presented) The stent according to claim 14 wherein the vessel support element and support rail are each coated with a different agent for delivery to the body.

20. (Previously Presented) The stent according to claim 14 wherein each of the rail support elements comprises a different agent for delivery to the body.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent Claim 1

The text of Claim 1 is repeated below in bold font and each portion is followed by a concise explanation in italic font identifying the source of the subject matter, including reference to the specification by page and line number.

A stent for introducing within a body comprising: a plurality of vessel support elements

" support elements 10 are made from medical-grade metal wire formed as a closed loop (i.e., as an annular hoop) in a known manner, including, for example, micro-welding two ends of a wire segment together." Specification, paragraph 39.

"Preferably, each support element 10 has a sinusoidal or otherwise undulating form, such as the rounded wave shape seen in FIG. 1 by way of example." Specification paragraph 40.

"The stent comprises a plurality of vessel support elements. A first one of the vessel support elements forms a first end support element and second one of the support elements forms a second end support element. The stent also comprises at least one support rail element extending between the end support elements. The support rail element includes a curved end section for extending beyond one of the end support elements. A plurality of the vessel support elements are moveable along and relative to the at least one support rail element." Specification at paragraph 14.

having at least one aperture therethrough

"the support elements 110 include apertures 117 in the curved members 116 through which the rails 120 extend as shown in FIG. 12. Apertures 117 extend through the peaks 112 in a direction that is substantially parallel to the length of the stent 100. These apertures 117 retain and orient the supporting rail(s) 120 in a direction parallel to the length of the stent 100." Specification at paragraph 67.

for the passage of at least one support rail,

"An example of a stent according to the present invention includes a helically wound stent element freely mounted on a plurality of flexible rail elements that extend along the length of the stent. Because the stent element is freely mounted on the rail elements, various portions of the stent element are free to slide along the rail elements." Specification, paragraph 8.

a first one of said vessel support elements forming a first end support element and second one of said support elements forming a second end support element; and

The stent comprises a plurality of vessel support elements. A first one of the vessel support elements forms a first end support element and second one of the support elements forms a second end support element. Specification, paragraph 14.

wherein the at least one support rail element extending between said end support elements and including a curved end section for extending beyond one of the end support elements,

As shown in FIG. 18, a preferred embodiment of the rail element 312 is a continuous member that includes a plurality of curved rail loop end sections and a plurality of elongated sections 314 that extend parallel to each other and the length of the stent when the stent is in at least its undeployed state (see FIG. 20). Specification, paragraph 74.

As shown in FIG. 18, adjacent elongated sections 314 are connected together by respective curved end sections 316 so that the rail element 312 forms the continuous, uninterrupted piece of elongated sections 314 and curved loop

sections 316 that extend along the different axes of the stent 300. These curved end sections 316 do not cause friction or trauma to the vessel during introduction, tracking or deployment of the stent 300. The curved end sections 316 can be provided at both ends of the stent 300 as shown in FIGS. 18 and 21. Additionally, as discussed below and shown in FIG. 19, the curved end sections 316 permit the terminus 340 of each elongated section 314 that is not integral with a curved end section 316 to be fixed to the outer support element 310 at the inner peaks 11 that are spaced from the outer peaks 11 of the outermost vessel support element 310. As a result, the termini 340 of the elongated sections 314 do not extend beyond the outermost longitudinal point of the outer vessel support element 310 (as shown in FIG. 19).." Specification, paragraph 74.

wherein a plurality of said vessel support elements are moveable along and relative to said at least one support rail element.

"An example of a stent according to the present invention includes a helically wound stent element freely mounted on a plurality of flexible rail elements that extend along the length of the stent. Because the stent element is freely mounted on the rail elements, various portions of the stent element are free to slide along the rail elements. Therefore, when the stent is placed in situ in a curved or otherwise bent blood vessel, the increased longitudinal flexibility of portions of the stent element along the axial extent of the stent allows those stent portions on the inside of the curve to move freely towards each other. On the other hand, the corresponding stent portions on the outside of the curve are free to move apart from each other. In this manner, the stent can more easily conform to the bend in the blood vessel and reduce the tendency of the stent to straighten the blood vessel." Specification, paragraph 8.

" For example, if the support elements 110 include ten peaks 112, then up to ten rails 120 could be used. In between the hoops 110 at the terminal ends 104, 106, the remaining hoops 110 that are connected to each other by the bridge elements 28 are free to move along the rail(s) 120. These remaining hoops 110 slide along the rail(s) 120 so that the stent 100 can conform to the shape of the blood vessel." Specification, paragraph 66.

" As a result, the support elements 310 of each embodiment are unsecured to the elongated sections 314 and thus can move anywhere along the elongated members 314 and the loop end sections 316." Specification, paragraph 78.

V. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

A. Rejection of Claims 1-12 under 35 U.S.C. § 102

The grounds of rejection to be reviewed on appeal is whether claims 1-12 are unpatentable under 35 U.S.C. 102(b) over U.S. Patent No. 5,938,695 to *Borghi et al.* (hereinafter "Borghi").

B. Rejection of claims 13 and 14 under 35 U.S.C. § 103

The grounds of rejection to be reviewed is whether claims 13 and 14 are unpatentable under 35 U.S.C. § 103(a) over Borghi in view of U.S. Patent No. 5,554, 181 to *Das, et al* (hereinafter "Das").

C. Rejection of claims 13 and 14 under 35 U.S.C. § 103

The grounds of rejection to be reviewed is whether claims 13 to 20 are unpatentable under 35 U.S.C. § 103(a) over Borghi in view of U.S. Patent No.6,224,626 to *Steinke, et al* (hereinafter "Steinke").

VI. ARGUMENT.

A. Rejection under 35 U.S.C. § 102(b) over U.S. Patent No. 7,177,415

Claims 1-12 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,938,695 to *Borghi* (" Borghi").

As stated in 35 U.S.C. §102(b), a person shall be entitled to a patent unless "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States,"

Applicants hereby appeal the Examiner's final rejection of Claims 1-12 under 102(b) on the basis that the Examiner failed to establish that every element of the rejected claims is present in the Borghi reference. A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P § 2131 citing to Verdegaal Bros. v. Union Oil Co. of California, 814, F. 2d 628, 631 (Fed. Cir. 1987). It is well settled that when rejecting claims under 35 U.S.C. §102, an Examiner must find that a single prior art reference discloses each and every element of the challenged claim. In re Donahue, 766 F.2d 531 (Fed. Cir. 1985); Getcher v. Davidson, 116 F.3d 1454, 1457 (Fed. Cir. 1997).

1. Claim 1

With respect to Claim 1, the Examiner contended that Borghi discloses a stent having a plurality of vessel support elements having an aperture through which a rail passes and wherein the vessel support elements are movable along and relative to the rail. The Borghi reference discloses a stent having a plurality of longitudinal elements, but it does not show support elements which are movable along and relative to the longitudinal elements.

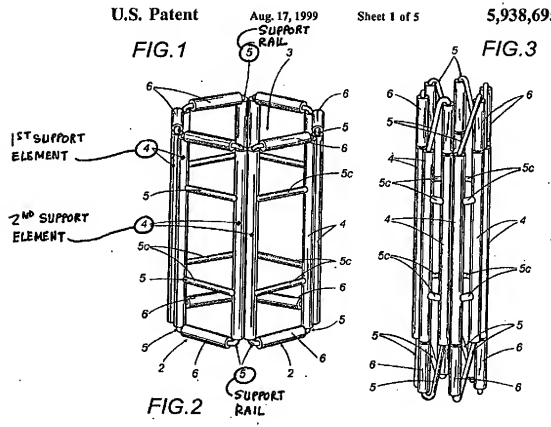
The most common definition of along means in parallel with from one end to the other.

*Along "1. through, on, beside, over, or parallel to the length or direction of; from one end to the other of; to walk along a highway; to run a border along a shelf. "*along.

Dictionary.com. *Dictionary.com Unabridged (v 1.1).* Random House, Inc. http://dictionary.reference.com/browse/along

The Examiner failed to show that the prior art reference of Borghi discloses each and every element of the challenged Claim 1 and, therefore, the rejection of Claim 1 on the basis of 35 U.S.C. §102(b) was in error.

The examiner has misunderstood the elements of the present invention on compared them to non analogous structures in Borghi. The examiner has construed elements 5 as the support rail and elements 4 as the support element as shown in his drawing from the December 12, 2007 office action at page 3.



In contrast, the present invention defines the rails as the longitudinal members and the support elements as radial members. Figure 18 is reproduced below for ease of reference. The rails are element 312 and the support elements are element 310.

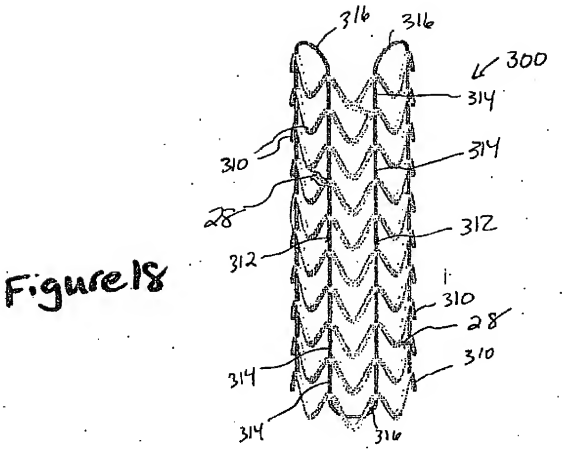


Figure 18

In contrast to the present invention, the alleged support elements 4 are longitudinal in nature and physically not capable of moving "along" the alleged rail 5 which in Borghi is used for holding the stent in its open configuration.

Borghi at Col. 3, lines 15-36 makes the function of elements 4 and 5 clear.

> *The filiform spacer elements 5 are inserted in and associated with the first tubular elements 4 in such a manner that the modular element 2 assumes a closed quadrangular shape of reducible proportions: this particular characteristic is attributable to the spacer elements 5, which are deformable along their longitudinal axis X (the definition applies even for a non rectilinear axis, in the event that the filiform material should present a shape other than cylindrical) so as to allow a variation in the distance D separating the first tubular elements 4 from a position of minimum clearance,*

in which the selfsame two elements 4 are substantially in mutual contact (as discernible clearly in FIGS. 3, 4 and 9) and the spacer elements 5 appear folded or looped, to a stable operating position of maximum clearance between the first tubular elements 4 (see FIGS. 1, 2 and 8), in which the spacer elements 5 are disposed at right angles to the first tubular elements 4. Each single module 2 is thus deformable within its respective plane, so that the resulting prismatic structure, in short, the endoprosthetic structure to which the invention relates, is rendered capable of contraction or expansion in the radial direction (see in particular FIGS. 1 to 4).

Simply put, the arrangement of the elements of Borghi is to move the stent from a narrow circumference for insertion to an expanded circumference upon deployment. As shown in Borghi, Figs. 1-4, the alleged support elements 4 are incapable of any movement along a rail. Similarly, the lognitudinal flexibility discussed in Borghi is merely to bring element 5 from its collapsed to its open position. There is no flexibility between the ends of the stent.

The present claims require a plurality of support elements which are positioned such that the rail extends between the two end support elements.

" *first one of said vessel support elements forming a first end support element and second one of said support elements forming a second end support element; and wherein the at least one support rail element extending between said end support elements*"

Borghi does not disclose any arrangement where two different support elements support the opposite ends of a rail. Instead, a single element 4 supports both ends of element 5. The present claim requires two elements to support opposite ends of the rail..

Borghi also fails to disclose any arrangement where a plurality of support elements are moveable along and relative to the rail. The part of Borghi are in a

fixed relationship other than the ability of element 5 to move between a collapsed and an expanded state.

2. Claim 2

Claim 2 depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 2. Borghi fails to disclose each and every element of challenged Claim 2, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 2.

3. Claim 3

Claim 3 depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 3. Borghi fails to disclose each and every element of challenged Claim 3, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 3.

4. Claim 4

Claim 4 depends from Claim 3 which depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 4. Borghi fails to disclose each and every element of challenged Claim 2, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 4.

5. **Claim 5**

Claim 5 depends from Claim 4, which depends from Claim 3 which depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 5. Borghi fails to disclose each and every element of challenged Claim 5, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 5.

Further Borghi does not show a single support rail element that extends upon multiple axis of the stent. Borghi only discloses a plurality of elements 5.

6. **Claim 6**

Claim 6 depends from Claim 2 which depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 6. Borghi fails to disclose each and every element of challenged Claim 6, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 6.

Further, Borghi fails to disclose a single elongated member which has terminal ends secured to one of the vessel support elements. The elements 5 in Borghi does not show a terminal end or an end of said element 5 secured to and element 4.

7. **Claim 7**

Claim 7 depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 7. Borghi fails to disclose each and every element of challenged Claim 7, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails

disclose two different support elements supporting the opposite ends of a rail as required in claim 7.

Borghi further fails to show a curved end section as required by Claim 7. The end sections of Borghi are by necessity angular to allow the sent to change radial conformation.

8. Claim 8

Claim 8 depends from Claim 7 which depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 8. Borghi fails to disclose each and every element of challenged Claim 8, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 8.

Borghi further fails to show a first end of an elongated section which is secured to a support element and a second end which is integral with a curved end.

9. Claim 9

Claim 9 depends from claim 8 which depends from Claim 7 which depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, or dependent claims 7 and 8, likewise Borghi does not disclose every element of dependent Claim 9. Borghi fails to disclose each and every element of challenged Claim 9, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 9.

Borghi further fails to disclose a first end of an elongated section which is secured to a support element and a second end which is integral with a curved end. Borghi also does not disclose an elongated section which is free of direct connection to a second end support element.

All of the alleged elongated support sections of Borghi terminate within an alleged support structure.

10. Claim 10

Claim 10 depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 10. Borghi fails to disclose each and every element of challenged Claim 10, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 9.

Borghi also fails to disclose a stent in which the support rail is secured to a support element positioned in between the terminal elements. The longitudinal support of Borghi only extends between two elements.

11. Claim 11

Claim 11 depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 2. Borghi fails to disclose each and every element of challenged Claim 2, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 11.

12. Claim 12

Claim 12 depends from Claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose

every element of dependent Claim 12. Borghi fails to disclose each and every element of challenged Claim 12, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Borghi fails disclose two different support elements supporting the opposite ends of a rail as required in claim 12.

Further, Borghi does not disclose a biocompatible coating over the support rail as required by the present claim and cannot anticpiate claim 12.

B. **Rejection under 35 U.S.C. § 103 over Borghi in view of U.S. Patent 5,554,181**

Claims 13-14 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,938,695 to *Borghi* (" Borghi") in view of U.S. Patent 5,554,181 to Das et al ("Das").

As stated in 35 U.S.C. §103(a), a person shall be entitled to a patent unless (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

1. The examiner did not make a prima facie case.

Applicants hereby appeal the Examiner's final rejection of Claims 13-14 under 103(a) on the basis that the Examiner failed to establish a prima facie case of obviousness in that that he has failed to show all of the elements of the present invention exist in the art. A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P § 2131 citing to Verdegaal Bros. v. Union Oil Co. of California, 814, F. 2d 628, 631 (Fed. Cir. 1987). It is well settled that when rejecting claims under 35 U.S.C. §102, an Examiner must find that a single prior art reference discloses each and every element of the challenged claim. In re Donahue, 766 F.2d 531 (Fed. Cir. 1985); Getcher v. Davidson, 116 F.3d 1454, 1457 (Fed. Cir. 1997).

It is well settled that it is the burden of the Examiner to establish a *prima facie* case of obviousness when rejecting claims under 35 U.S.C. § 103. *In re Reuter*, 651 F.2d 751 (CCPA 1981); MPEP § 2142. If a *prima facie* case of obviousness is not established, a rejection under 35 U.S.C. § 103 is improper and the Applicant need not present evidence of non-obviousness to overcome such a rejection. *Id.*

In order to establish a *prima facie* case of obviousness, the Examiner must cite to prior art that teaches or suggests all claim limitations. *In re Royka*, 490 F.2d 981 (CCPA 1974) (emphasis is added); M.P.E.P. § 2143.03. All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970); MPEP § 2143.03. The Examiner has failed to show that the prior art references teach or suggest all claim limitations as the references do not teach or suggest a stent having the claimed elements.

Claim 13

Claim 13 depends from Claim 1 and therefore has all of the limitations of claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 13. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n).

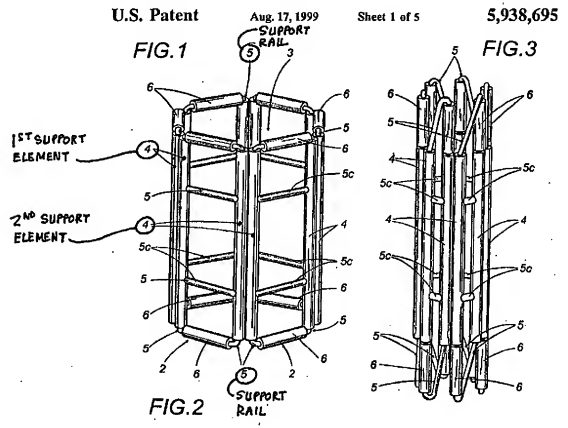
With respect to Claim 13, the Borghi reference discloses a stent having a plurality of longitudinal elements, but it does not show support elements which are movable along and relative to the longitudinal elements.

The most common definition of along means in parallel with from one end to the other.

*Along "1. through, on, beside, over, or parallel to the length or direction of; from one end to the other of; to walk along a highway; to run a border along a shelf. "*along. Dictionary.com. *Dictionary.com Unabridged (v 1.1).* Random House, Inc. http://dictionary.reference.com/browse/along

The Examiner failed to show that the prior art reference of Borghi discloses each and every element of the challenged Claim 1 and, therefore, the rejection of Claim 1 on the basis of 35 U.S.C. §103 was in error.

The Examiner has misunderstood the elements of the present invention on compared them to non analogous structures in Borghi. The Examiner has construed elements 5 as the support rail and elements 4 as the support element as shown in his drawing from the December 12, 2007 office action at page 3.



In contrast, the present invention defines the rails as the longitudinal members and the support elements as radial members. Figure 18 is reproduced below for ease of reference. The rails are element 312 and the support elements are element 310.

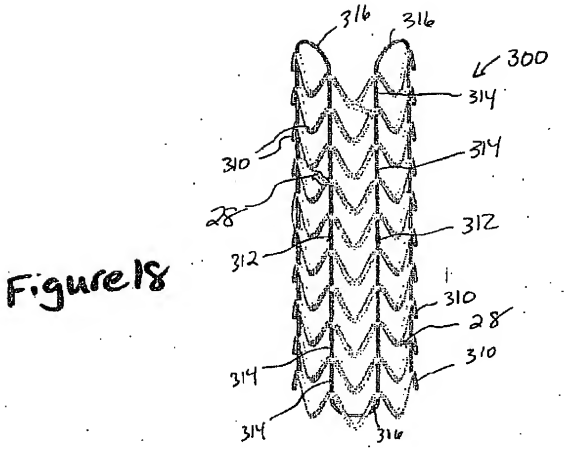


Figure 18

In contrast to the present invention, the alleged support elements 4 are longitudinal in nature and physically not capable of moving "along" the alleged rail 5 which in Borghi is used for holding the stent in its open configuration.

Borghi at Col. 3, lines 15-36 makes the function of elements 4 and 5 clear.

> *The filiform spacer elements 5 are inserted in and associated with the first tubular elements 4 in such a manner that the modular element 2 assumes a closed quadrangular shape of reducible proportions: this particular characteristic is attributable to the spacer elements 5, which are deformable along their longitudinal axis X (the definition applies even for a non rectilinear axis, in the event that the filiform material should present a shape other than cylindrical) so as to allow a variation in the distance D separating the first tubular elements 4 from a position of minimum clearance,*

in which the selfsame two elements 4 are substantially in mutual contact (as discernible clearly in FIGS. 3, 4 and 9) and the spacer elements 5 appear folded or looped, to a stable operating position of maximum clearance between the first tubular elements 4 (see FIGS. 1, 2 and 8), in which the spacer elements 5 are disposed at right angles to the first tubular elements 4. Each single module 2 is thus deformable within its respective plane, so that the resulting prismatic structure, in short, the endoprosthetic structure to which the invention relates, is rendered capable of contraction or expansion in the radial direction (see in particular FIGS. 1 to 4).

Simply put, the arrangement of the elements of Borghi is to move the stent from a narrow circumference for insertion to an expanded circumference upon deployment. As shown in Borghi, Figs. 1-4, the alleged support elements 4 are incapable of any movement along a rail. Similarly, the lognitudinal flexibility discussed in Borghi is merely to bring element 5 from its collapsed to its open position. There is no flexibility between the ends of the stent.

The present claims require a plurality of support elements which are positioned such that the rail extends between the two end support elements.

" first one of said vessel support elements forming a first end support element and second one of said support elements forming a second end support element; and wherein the at least one support rail element extending between said end support elements"

Borghi does not disclose any arrangement where two different support elements support the opposite ends of a rail. Instead, a single element 4 supports both ends of element 5. The present claim requires two elements to support opposite ends of the rail..

Borghi also fails to disclose any arrangement where a plurality of support elements are moveable along and relative to the rail. The part of Borghi are in a

fixed relationship other than the ability of element 5 to move between a collapsed and an expanded state.

As discussed above, Borghi does not disclose all of the claimed elements. The stent in Borghi does not have the relationship between the cited rail and support elements required by the present claims. Das does not correct the deficiencies of Borghi, namely it does not disclose a stent having the claimed relationship between the rail and support elements. The Examiner is correct that Das discloses drug coating a stent and cites Col. 8, lines 16-25 disclosing heparin and fibrin coatings. However, the combination of Borghi and Das do not result in the present invention.

One of skill in the art would not be motivated to build a drug coated stent as required by claim 13. Notably, Borghi discloses a stent in which only a single support element runs longitudinally on the stent. Borghi was trying to solve the problem of how to maximize the radial strength of the stent by designing a stent which avoided the properties of the present invention.

> "It is known and scientifically proven that the successful manufacture of coronary endoprostheses guaranteeing both safety over time and operational efficiency is dependent on key requirements linked to mechanical and physiological factors: firstly, there is the need to ensure a sound resistance to radial deformation, given that the artery functions as a means of conveying blood under pressure and in consequence is subjected to a pressor action that the stent must be able to withstand; and secondly, there must be no effects generated that may upset the normal functioning of the artery." Borghi, col. 1, lines 57-67.

> "In view of this second requirement, it is in fact inadvisable to fashion a stent exhibiting extensive surfaces fragmented by relative slots or openings; over time, these can create interstices favouring the build-up of atherosclerotic plaque, of which the physical impact is not inconsiderable. On the other hand, compact stents fashioned with extensive contact surfaces and more consistent thicknesses can lead to the risk of thrombosis." Borghi, col. 2, lines 1-10.

The present invention is concerned with longitudinal flexibility.

"The present invention is directed to an intraluminal stent having increased longitudinal flexibility when compared to prior art stents. Longitudinal flexibility as used herein relates to the flexibility of the stent structure (or portions thereof) to move relative to its major, longitudinal axis of extension." Specification, paragraph 007.

Borghi is completely silent on longitudinal flexibility. Borghi is in fact part of the art that creates the problems the present invention is trying to solve.

"Conventional, longitudinally inflexible stents are disclosed in, for example, U.S. Pat. No. 6,113,628 to Borghi and U.S. Pat. No. 5,653,727 to Wiktor. The stents discussed in these patents are not capable of achieving the longitudinal flexibility needed to prevent restenosis. These stents include circumferential vascular support elements (sometimes referred to as "hoops") that are securely spaced from each other and from the ends of the stent so that they do not experience relative axial movement. The spacing between adjacent support elements is maintained by rigid connections or bridge elements (sometimes referred to in the art as "bridges") that extend between adjacent support elements and/or a rigid connection between each support element and at least one longitudinal rail that extends from a first end of the stent to a second end of the stent. This type of secure, rigid spacing prevents the support elements from moving longitudinally along the rail(s) of the stent and prevents the stent from conforming to the curvature of the blood vessel in which it is deployed. Specification, paragraph 005.

While the M.P.E.P. provides that prior art can be modified or combined to reject claims as *prima facie* obviousness as long as there is a reasonable expectation of success. M.P.E.P. §2143.02 citing to *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986). Obviousness does not require absolute predictability; however, at least some degree of predictability is required. M.P.E.P. §2143.02. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. M.P.E.P. §2143.02 citing to *In re Rinehart*, 531 F.2d 1048 (CCPA 1976).

Instead of providing predictability, Borghi in fact teaches away from the present design on the basis of its mechanical properties. The present invention relies upon the conventional stent technology consisting of "extensive surfaces fragmented by relative slots or openings" and even introduces more openings in the form of apertures to allow the rail to pass through.

One of skill in the art would not have been motivated to combine Das with Borghi to achieve a stent having longitudinal flexibility and a drug coating.

Claim 14

Claim 14 depends from Claim 1 and therefore has all of the limitations of claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 14. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n).

The short comings of Borghi have been discussed under claim 13 and are incorporated by reference. Das does not teach the use of a base material which is not biocompatible. The present specification defines base material to include a material which is not biocompatible.:

> *The term "biocompatible" refers to materials that do not have toxic or injurious effects on biological systems. Thus, the stents should not substantially induce inflammatory and neointimal responses. Any of the biocompatible materials discussed below may be used as the primary material to form the rails or other portions of the disclosed stents, or may be used to form a film, coating, or layer to cover a base material (e.g., a metal) that may or may not be biocompatible. Specification, paragraph 082.*

As such Das does not remedy the deficiencies of Borghi and taken together these references do not disclose all of the required elements of claim 14.

C. <u>Rejection of claims 13 -20 under 35 U.S.C. § 103</u>

The grounds of rejection to be reviewed is whether claims 13 to 20 are unpatentable under 35 U.S.C. § 103(a) over Borghi in view of U.S. Patent No.6,224,626 to *Steinke, et al* (hereinafter "Steinke")

Claim 13.

Claim 13 depends from Claim 1 and therefore has all of the limitations of claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 14. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). Steinke does not correct the deficiencies of Borghi.

While the Examiner has correctly noted that Steinke includes a laundry list of drugs suitable for coating a stent at Col 10, lines 8-33, there is no allegation that Steinke corrects the mechanical deficiencies of Borghi. Taken together, Borghi and Steinke do not disclose a stent having a plurality of support elements positioned on a longitudinal rail. As such all of the required elements of claim 13 are not present in the references.

Claim 14

Claim 14 depends from Claim 1 and therefore has all of the limitations of claim 1. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 14. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 14 are not present.

Claim 15.

Claim 15 depends from Claim 13, which depends from Claim 1 and therefore has all of the limitations of claims 1 and 13. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 14. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The

shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 15 are not present.

Further claim 15 requires that the support rails consist of a polymer comprising at least one agent for delivery to the body. Neither Borghi nor Steinke suggest that the rails themselves can be made from a polymer. As such all of the required elements of Claim 15 are not present.

Claim 16

Claim 16 depends from Claim 13, which depends from Claim 1 and therefore has all of the limitations of claims 1 and 13. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 16. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 16 are not present.

Further, there is no suggestion in Steinke or Borghi to coat the support elements and the rails with a different agent for delivery to the body. As such Borghi and Steinke cannot render Claim 16 obvious because Claim 16 requires that the support elements and the rails each deliver a different active agent.

Claim 17

Claim 17 depends from Claim 13, which depends from Claim 1 and therefore has all of the limitations of claims 1 and 13. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 17. Borghi fails to disclose each and every element of

challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 17 are not present.

Further, there is no suggestion in Steinke or Borghi to make a stent wherein each of the rail support elements delivers a different drug to the body. As such Borghi and Steinke cannot render Claim 17 obvious because Claim 17 requires that each rail support element delivers a different active agent.

Claim 18

Claim 18 depends from Claim 14, which depends from Claim 1 and therefore has all of the limitations of claims 1 and 14. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 18. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests a stent having the claimed relationship between the rail and support elements or that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 18 are not present.

Claim 19

Claim 19 depends from Claim 14, which depends from Claim 1 and therefore has all of the limitations of claims 1 and 14. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 19. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the

claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests a stent having the claimed relationship between the rail and support elements or that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 19 are not present.

Further, there is no suggestion in Steinke or Borghi to coat the support elements and the rails with a different agent for delivery to the body. As such Borghi an Steinke cannot render Claim 19 obvious because Claim 19 requires that the support elements and the rails each deliver a different active agent.

Claim 20

Claim 20 depends from Claim 14, which depends from Claim 1 and therefore has all of the limitations of claims 1 and 14. For the same reasons noted above that Borghi does not disclose every element of the challenged independent Claim 1, likewise Borghi does not disclose every element of dependent Claim 20. Borghi fails to disclose each and every element of challenged Claim 13, as a dependent claim shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. M.P.E.P. §608.01(n). The shortcomings of Borghi and Steinke have been addressed in Claim 13 above. Neither reference suggests that the stent can be made of a base material which is not biocompatible. As such all of the required elements of Claim 20 are not present.

Further, there is no suggestion in Steinke or Borghi to make a stent wherein each of the rail support elements delivers a different drug to the body. As such Borghi and Steinke cannot render Claim 20 obvious because Claim 20 requires that each rail support element delivers a different active agent.

D. CONCLUSION

It has been shown that *Borghi* cannot be said to anticipate the present invention under 35 U.S.C. § 102(b) because *Borghi* does not teach or disclose every element of each rejected Claims 1-12. The Examiner misconstrued the Borghi reference as teaching a stent having support elements at either end of a rail.

It has also been shown that claims 13 and 14 are not obvious under 35 U.S.C. §103 over Borghi in view of Das in that Das does not remedy the structural defects of Borghi.

It has also been shown that claims 12 to 20 are not obvious under 35 U.S.C. §103 over Borghi in view of Steinke in that Steinke does not remedy the structural defects of Borghi.

It is therefore respectfully submitted that the rejection under 35 U.S.C. § 102 and 35 U.S.C. § 103 have been overcome and should be reversed by the Board.

VII. CLAIMS APPENDIX.

1. A stent for introducing within a body comprising: a plurality of vessel support elements having at least one aperture therethrough for the passage of at least one support rail, a first one of said vessel support elements forming a first end support element and second one of said support elements forming a second end support element; and wherein the at least one support rail element extending between said end support elements and including a curved end section for extending beyond one of the end support elements, wherein a plurality of said vessel support elements are moveable along and relative to said at least one support rail element.

2. The stent according to claim 1, wherein said at least one support rail element includes a plurality of curved end sections.

3. The stent according to claim 2, wherein said at least one support rail element includes a plurality of elongated sections extending between the curved end sections located at opposite ends of said stent.

4. The stent according to claim 3, wherein said elongated sections are integrally connected to each other by respective curved end sections.

5. The stent according to claim 4, wherein said stent includes a single support rail element that extends along multiple axes of said stent, said axes being substantially parallel to the longitudinal axis of the stent.

6. The stent according to claim 2, wherein said at least one support rail element includes a single elongated member extending between respective curved end sections, and wherein said respective curved end sections have terminal ends secured to a respective one of said vessel support elements.

7. The stent according to claim 1, wherein said at least one support rail element comprises a plurality of elongated sections and a curved section extending between said elongated sections.

8. The stent according to claim 7, wherein said elongated sections each have a first end secured to the first end support element and a second end integral with said curved section.

9. The stent according to claim 8, wherein said second ends of said elongated sections are free of a direct connection to said second end support element.

10. The stent according to claim 1, wherein said at least one support rail element comprises a support rail element that has a terminus secured to a vessel support element positioned between said first end support element and said second end support element.

11. The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a biocompatible material.

12. The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a base material having a biocompatible covering.

13. The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising at least one agent for delivery to the body.

14. The stent according to claim 1, wherein at least one of said vessel support elements or at least one of said support rail elements comprising a base material having a coating of at least one agent for delivery to the body.

15. The stent according to claim 13 wherein the support rails consist of a polymer comprising at least one agent for delivery to the body.

16. The stent according to claim 13 wherein the vessel support element and support rail are each coated with a different agent for delivery to the body.

17. The stent according to claim 13 wherein each of the rail support elements comprises a different agent for delivery to the body.

18. The stent according to claim 14 wherein the support rails consist of a polymer comprising at least one agent for delivery to the body.

19. The stent according to claim 14 wherein the vessel support element and support rail are each coated with a different agent for delivery to the body.

20. The stent according to claim 14 wherein each of the rail support elements comprises a different agent for delivery to the body.

VIII. EVIDENCE APPENDIX.

None.

IX. RELATED PROCEEDINGS APPENDIX.

None.

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Respectfully submitted,

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